

Cablivi® (caplacizumab-yhdp)

When requesting Cablivi® (caplacizumab-yhdp), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indication

Cablivi is indicated for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy.

Coverage Guidelines

Acquired Thrombotic Thrombocytopenic Purpura (aTTP)

The individual must meet **all** of the following criteria for approval:

- The individual is currently receiving at least one immunosuppressive therapy (e.g., systemic corticosteroids, rituximab or rituximab product, cyclosporine, cyclophosphamide, mycophenolate mofetil, hydroxychloroquine, Velcade [bortezomib for injection]); AND
- The individual is 18 years of age or older; AND
- Cablivi is prescribed by or in consultation with a hematologist; AND
- Cablivi was initiated in the inpatient setting in combination with plasma exchange; AND
- If the patient has previously received Cablivi, the patient has not had more than two recurrences of aTTP while on Cablivi.

Approval duration: 2 months

Dosing Recommendations

Cablivi should be administered upon the initiation of plasma exchange therapy.

The recommended dose of Cablivi is as follows:

- First day of treatment: 11 mg bolus intravenous injection at least 15 minutes prior to plasma exchange followed by an 11 mg subcutaneous injection after completion of plasma exchange on day 1
- Subsequent treatment during daily plasma exchange: 11 mg subcutaneous injection once daily following plasma exchange
- Do not exceed 60 doses following the last plasma exchange session.

References

1. Cablivi® for injection [prescribing information]. Cambridge, MA: Genzyme Corporation; October 2021.
2. Duggan S. Caplacizumab: first global approval. *Drugs*. 2018;78:1639-1642.
3. Coppo P, Cuker A, George JN. Thrombotic thrombocytopenic purpura: toward targeted therapy and precision medicine. *Res Pract Thromb Haemost*. 2019;3:26-37.
4. Joly BS, Coppo P, Veyradier A. Thrombotic thrombocytopenic purpura. *Blood*. 2017;129:2836-2846.
5. Zheng XL, Vesely SK, Cataland SR, et al. International Society on Thrombosis and Haemostasis (ISTH) guidelines for the diagnosis of thrombotic thrombocytopenic purpura. *J Thromb Haemost*. 2020;18:2486-2495.
6. Scully M, Cataland SR, Peyvandi F, et al. Caplacizumab treatment for acquired thrombotic thrombocytopenic purpura. *N Engl J Med*. 2019;380:335-346.
7. Scully M, Hunt BJ, Benjamin S, et al. Guidelines on the diagnosis and management of thrombotic thrombocytopenic purpura and other thrombotic microangiopathies. *Br J Haematol*. 2012;158:323-335.
8. Zheng XL, Vesely SK, Cataland SR, et al. International Society on Thrombosis and Haemostasis (ISTH) guidelines for the treatment of thrombotic thrombocytopenic purpura. *J Thromb Haemost*. 2020;18:2496-2502.